AMENDMENTS

IN THE CLAIMS:

Please amend claims 1, 65 and 83 and add new claims 109, 110 and 111. The remaining claims are reiterated below for the convenience of the Examiner.

1. (Currently Amended) A device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, said device comprising:

at least one physiological fluid flow rate characterization element for measuring the flow rate of physiological fluid at said site;

at least one skin-piercing element for accessing said physiological fluid at said site; and

means for determining whether said site is suitable for sampling physiological fluid for use in said ~~insaid~~ analyte concentration determination test based on said measured flow rate of physiological fluid at said site.

2. (Previously Presented) The device according to claim 1, wherein said at least one physiological fluid flow rate characterization element comprises an element capable of determining the temperature of said physiological fluid at said site.

3. (Previously Presented) The device according to claim 1, wherein said at least one physiological fluid flow rate characterization element comprises an element capable of determining red blood cell character of said physiological fluid at said site.

4. (Previously Presented) The device according to claim 1, wherein said at least one physiological fluid flow rate characterization element comprises at least one light source for irradiating tissue with light and at least one detector for detecting the light absorbed by said tissue.

5. (Original) The device according to claim 4, wherein at least one light source is capable of emitting light at a wavelength in the range from about 400 nm to 1200 nm.

6. (Original) The device according to claim 1, wherein said at least one flow

characterization element comprises an element capable of performing Doppler flowmetry.

7. (Cancel)

8. (Original) The device according to claim 1, further comprising an analyte concentration determination reagent test strip.

9. (Original) The device according to claim 8, wherein said test strip is an electrochemical test strip.

10. (Original) The device according to claim 8, wherein said test strip is a colorimetric test strip.

11. (Previously Presented) The device according to claim 1, further comprising a means for automatically determining the concentration of at least one analyte in said physiological fluid.

12. (Original) The device according to claim 1, further comprising at least one fluid enhancing element.

13. (Previously Presented) The device according to claim 1, further comprising at least one physiological fluid sample type characterization element.

14. (Previously Presented) The device according to claim 13, wherein said at least one physiological fluid sample type characterization element comprises a pulse characterization element.

15. (Previously Presented) The device according to claim 13, wherein said at least one physiological fluid sample type characterization element comprises a hemoglobin characterization element.

16. (Previously Presented) A device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, said device comprising:

at least one physiological fluid sample type characterization element for determining whether a

site comprises arterial fluid, venous fluid or interstitial fluid;

at least one skin-piercing element for accessing said physiological fluid at said site.; and

means for determining whether said site is suitable for sampling physiological fluid for use in said analyte concentration determination test, based on said determined fluid type.

17. (Previously Presented) The device according to claim 16, wherein said at least one physiological fluid sample type characterization element comprises at least one light source for irradiating tissue with light and at least one detector for detecting the light absorbed by said tissue.

18. (Original) The device according to claim 17, wherein said at least one light source is capable of emitting light at a wavelength from about 400 nm to 1200 nm.

19. (Original) The device according to claim 17, wherein said at least one light source includes at least two light sources.

20. (Original) The device according to claim 19, wherein each of said at least two light sources is capable of emitting light at a wavelength from about 400 nm to 1200 nm.

21. (Previously Presented) The device according to claim 16, wherein said at least one physiological fluid sample type characterization element comprises an element capable of determining the pulse character of said site.

22. (Previously Presented) The device according to claim 16, wherein said at least one physiological fluid sample type characterization element comprises an element capable of determining the hemoglobin character of said physiological fluid at said site.

23. (Previously Presented) The device according to claim 16, wherein said at least one physiological fluid sample type characterization element comprises an element capable of determining the hemoglobin concentration of said physiological fluid at said site.

24. (Previously Presented) The device according to claim 16, wherein said at least one physiological fluid sample type characterization element comprises an element capable of determining

the concentration of oxygenated hemoglobin and deoxygenated hemoglobin of said physiological fluid at said site.

25. (Previously Presented) The device according to claim 16, wherein said at least one physiological fluid sample type characterization element comprises an element capable of determining the concentration of total hemoglobin of said physiological fluid at said site.

26. (Previously Presented) The device according to claim 16, wherein said at least one physiological fluid sample type characterization element comprises an element capable of determining the oxygenated hemoglobin to deoxygenated hemoglobin ratio of said physiological fluid at said site.

27. (Cancel)

28. (Original) The device according to claim 16, further comprising an analyte concentration determination reagent test strip.

29. (Original) The device according to claim 28, wherein said test strip is an electrochemical test strip.

30. (Original) The device according to claim 28, wherein said test strip is a colorimetric test strip.

31. (Previously Presented) The device according to claim 16, further comprising a means for automatically determining the concentration of at least one analyte in said physiological fluid.

32. (Original) The device according to claim 16, further comprising at least one fluid enhancing element.

33. (Previously Presented) The device according to claim 16, further comprising at least one physiological fluid flow rate characterization element.

34. (Previously Presented) The device according to claim 33, wherein said at least one

physiological fluid flow rate characterization element comprises a pulse characterization element.

35. (Previously Presented) The device according to claim 33, wherein said at least one physiological fluid flow rate characterization element comprises a hemoglobin characterization element.

36. (Previously Presented) A device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, said device comprising:

at least one physiological fluid flow rate characterization element for measuring the flow rate of physiological fluid at said site;

at least one physiological fluid sample type characterization element for determining whether said site comprises arterial fluid, or venous fluid or interstitial fluid; and

means for determining whether said site is suitable for sampling physiological fluid for use in said analyte concentration determination test, based on the measured flow rate of physiological fluid at said site and based on the determined fluid type at said site.

37. (Previously Presented) The device according to claim 36, wherein said at least one of said physiological fluid flow rate characterization element and said physiological fluid sample type characterization element comprises at least one light source and at least one detector.

38. (Previously Presented) The device according to claim 36, wherein said at least one physiological fluid flow rate characterization element comprises a temperature characterization element.

39. (Previously Presented) The device according to claim 36, wherein said at least one physiological fluid flow rate characterization element comprises a red blood cell characterization element.

40. (Previously Presented) The device according to claim 36, wherein said at least one physiological fluid sample type characterization element comprises a pulse characterization element.

41. (Previously Presented) The device according to claim 36, wherein said at least one physiological fluid sample type characterization element comprises a hemoglobin characterization element.

42. (Cancel)

43. (Original) The device according to claim 36, further comprising an analyte concentration determination reagent test strip.

44. (Original) The device according to claim 43, wherein said test strip is an electrochemical test strip.

45. (Original) The device according to claim 43, wherein said test strip is a colorimetric test strip.

46. (Original) The device according to claim 36, further comprising a means for automatically determining the concentration of at least one analyte in said physiological sample.

47. (Original) The device according to claim 36, further comprising at least one skin-piercing element.

48. (Original) The device according to claim 36, further comprising at least one fluid enhancing element.

49. (Previously Presented) A method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, said method comprising the steps of:

measuring the flow rate of physiological fluid at a potentially suitable site; and

determining whether said potentially suitable site is suitable for sampling physiological fluid for use in said analyte concentration determination test, based on said measured flow rate.

50. (Previously Presented) The method according to claim 49, wherein said step of measuring the flow rate of said physiological fluid at said potentially suitable site comprises characterizing the temperature of said physiological fluid at said potentially suitable site.

51. (Previously Presented) The method according to claim 49, wherein said step of measuring the flow rate of said physiological fluid at said potentially suitable site comprises determining the red blood cell character of said potentially suitable site.

52. (Previously Presented) The method according to claim 51, wherein said step of determining the red blood cell character of said site comprises irradiating said potentially suitable site with light and detecting the light absorbed by said physiologically suitable site.

53. (Original) The method according to claim 51, wherein said step of determining the red blood cell character of said site comprises characterizing the red blood cell flux of said site.

54. (Previously Presented) The method according to claim 49, wherein said step of measuring the flow rate of said physiological fluid at said potentially suitable site comprises employing Doppler flowmetry techniques.

55. (Previously Presented) The method according to claim 49, further comprising the step of determining the type of physiological fluid at said potentially suitable site.

56. (Previously Presented) The method according to claim 55, wherein said step of determining the type of physiological fluid at said potentially suitable site comprises characterizing the pulse of said site.

57. (Previously Presented) The method according to claim 55, wherein said step of determining the type of physiological fluid at said potentially suitable site comprises characterizing the hemoglobin of said physiological fluid at said site.

58. (Original) The method according to claim 49, further comprising the step of accessing said physiological fluid at said suitable sampling site.

59. (Original) The method according to claim 49, further comprising the step of stimulating the site to enhance the volume of fluid expressed from said site.

60. (Original) The method according to claim 49, further comprising the step of determining the concentration of at least one analyte in said physiological sample.

61. (Original) The method according to claim 60, wherein said concentration determination comprises transferring said physiological sample to an analyte concentration test strip.

62. (Original) The method according to claim 60, wherein said at least one analyte is glucose and said physiological sample is blood.

63. (Original) The method according to claim 60, wherein said at least one analyte is glucose and said physiological sample is interstitial fluid.

64. (Original) The method according to claim 60, wherein an automated meter performs said concentration determination automatically.

65. (Currently Amended) A method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, said method comprising the steps of:

(a) contacting a potentially suitable site with a device configured to determine the type of physiological fluid at said potentially suitable site;

(b a) determining the type of physiological fluid at said ~~a~~ potentially suitable site; and

(c) determining whether said potentially suitable site is suitable for sampling physiological fluid for use in said analyte concentration determination test, based on said determined fluid type.

66. (Previously Presented) The method according to claim 65, wherein said step of determining the type of physiological fluid at said site comprises characterizing the pulse of said site.

67. (Original) The method according to claim 66, wherein the step of characterizing the pulse of said site comprises characterizing the red blood cell character of said site.

68. (Previously Presented) The method according to claim 67, wherein the step of characterizing the red blood cell character of said site comprises characterizing the red blood cell flux of

said site.

69. (Previously Presented) The method according to claim 65, wherein said step of determining the type of physiological fluid at said site comprises characterizing the hemoglobin character of physiological fluid at said site.

70. (Previously Presented) The method according to claim 69, wherein the step of characterizing the hemoglobin character of said physiological fluid at said site comprises determining the hemoglobin concentration of said physiological fluid at said site.

71. (Previously Presented) The method according to claim 69, wherein the step of characterizing the hemoglobin character of said physiological fluid at said site comprises determining the concentration of the oxygenated hemoglobin and deoxygenated hemoglobin of said physiological fluid at said site.

72. (Previously Presented) The method according to claim 69, wherein the step of characterizing the hemoglobin character of said physiological fluid at said site comprises determining the oxygenated hemoglobin to deoxygenated hemoglobin ratio of said physiological fluid at said site.

73. (Previously Presented) The method according to claim 65, further comprising the step of measuring the flow rate of said physiological fluid at said potentially suitable site.

74. (Previously Presented) The method according to claim 73, wherein said step of measuring the flow rate of said physiological fluid at said site comprises characterizing the temperature of said physiological fluid at said site.

75. (Previously Presented) The method according to claim 73, wherein said step of measuring the flow rate of said physiological fluid at said site comprises characterizing the red blood cell character of said site.

76. (Original) The method according to claim 65, further comprising the step of accessing said physiological fluid at said suitable sampling site.

77. (Original) The method according to claim 65, further comprising the step of stimulating the site to enhance the volume of fluid expressed from said site.

78. (Original) The method according to claim 65, further comprising the step of determining the concentration of at least one analyte in said physiological sample.

79. (Original) The method according to claim 78, wherein said concentration determination comprises transferring said physiological sample to an analyte concentration test strip.

80. (Original) The method according to claim 78, wherein said at least one analyte is glucose and said physiological sample is blood.

81. (Original) The method according to claim 78, wherein said at least one analyte is glucose and said physiological sample is interstitial fluid.

82. (Original) The method according to claim 78, wherein an automated meter performs said concentration determination automatically.

83. (Currently Amended) A method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, said method comprising the steps of:

measuring the flow rate of physiological fluid at a potentially suitable site;

determining the type of physiological fluid of said potentially suitable site ; and

determining whether said potentially suitable site is suitable for sampling physiological fluid for use in said analyte concentration determination test, based on said measured flow rate of physiological fluid and based on said determined fluid type at said site.

84. (Previously Presented) The method according to claim 83, wherein said step of measuring the flow rate of said physiological fluid at said potentially suitable site comprises characterizing the temperature of said physiological fluid at said potentially suitable site.

85. (Previously Presented) The method according to claim 83, wherein said step of measuring the flow rate of said physiological fluid at said potentially suitable site comprises determining the red blood cell character of said potentially suitable site.

86. (Original) The method according to claim 85, wherein said step of determining the red blood cell character of said site comprises irradiating said physiologically suitable site with light and detecting the light absorbed by said physiologically suitable site.

87. (Original) The method according to claim 85, wherein said step of determining the red blood cell character of said site comprises characterizing the red blood cell flux of said site.

88. (Previously Presented) The method according to claim 83, wherein said step of measuring the flow rate of said physiological fluid at said potentially suitable site comprises employing Doppler flowmetry techniques.

89. (Previously Presented) The method according to claim 83, wherein said step of determining the type of physiological fluid at said site comprises characterizing the pulse of said site.

90. (Original) The method according to claim 89, wherein the step of characterizing the pulse of said site comprises characterizing the red blood cell character of said site.

91. (Original) The method according to claim 90, wherein the step of characterizing the red blood cell character of said site comprises characterizing the red blood cell flux of said site.

92. (Previously Presented) The method according to claim 83, wherein said step of determining the type of physiological fluid at said site comprises characterizing the hemoglobin character of said physiological fluid at said site.

93. (Previously Presented) The method according to claim 92, wherein the step of characterizing the hemoglobin character of said physiological fluid at said site comprises determining the hemoglobin concentration of said physiological fluid at said site.

94. (Previously Presented) The method according to claim 92, wherein the step of characterizing the hemoglobin character of said physiological fluid at said site comprises determining the concentration of the oxygenated hemoglobin and deoxygenated hemoglobin of physiological fluid at said site.

95. (Previously Presented) The method according to claim 92, wherein the step of characterizing the hemoglobin character of said physiological fluid at said site comprises determining the oxygenated hemoglobin to deoxygenated hemoglobin ratio of said physiological fluid at said site.

96. (Original) The method according to claim 83, further comprising the step of accessing said physiological fluid at said suitable sampling site.

97. (Original) The method according to claim 83, further comprising the step of stimulating the site to enhance the volume of fluid expressed from said site.

98. (Original) The method according to claim 83, further comprising the step of determining the concentration of at least one analyte in said physiological sample.

99. (Original) The method according to claim 98, wherein said concentration determination comprises transferring said physiological sample to an analyte concentration test strip.

100. (Original) The method according to claim 98, wherein said at least one analyte is glucose and said physiological sample is blood.

101. (Original) The method according to claim 98, wherein said at least one analyte is glucose and said physiological sample is interstitial fluid.

102. (Original) The method according to claim 98, wherein an automated meter performs said concentration determination automatically.

103. (Previously Presented) A kit for determining a site for sampling physiological fluid, said kit comprising:

(a) at least one device selected from the group consisting of:

i. a device according to claim 1,

ii. a device according to claim 16, and

iii. a device according to claim 36; and

(b) instructions for using said device.

104. (Original) The kit according to claim 103, further comprising at least one skin-piercing element.

105. (Original) The kit according to claim, 103, further comprising at least one fluid stimulating element.

106. (Original) The kit according to claim 103, further comprising at least one analyte concentration characterization reagent test strip.

107. (Original) The kit according to claim 103, further comprising at least one meter for automatically determining the concentration of an analyte in said physiological sample.

108. (Original) A kit for determining the analyte concentration of a physiological sample, said kit comprising:

a plurality of devices selected from the group consisting of:

i. a plurality of devices according to claim 1,

ii. a plurality of devices according to claim 16, and

iii. a plurality of devices according to claim 36.

109. (New) A method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, said method comprising the steps of:

(a) determining the type of physiological fluid at a potentially suitable site, wherein said determining comprises characterizing the pulse of said potentially suitable site; and

(b) determining whether said potentially suitable site is suitable for sampling physiological fluid for use in said analyte concentration determination test, based on said determined type of physiological fluid.

110. (New) A method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, said method comprising the steps of:

(a) determining the type of physiological fluid at a potentially suitable site, wherein said determining comprises characterizing the hemoglobin character of physiological fluid at said potentially site; and

(b) determining whether said potentially suitable site is suitable for sampling physiological fluid for use in said analyte concentration determination test, based on said determined type of physiological fluid.

111. (New) A method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, said method comprising the steps of:

(a) determining the type of physiological fluid at a potentially suitable site;

(b) measuring the flow rate of physiological fluid at said potentially suitable site; and

(c) determining whether said potentially suitable site is suitable for sampling physiological fluid for use in said analyte concentration determination test, based on said determined type and flow rate of physiological fluid.